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January 22, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20857

Re: OMB Control Number 0910-0053; 21CFR 361.1

Dear Sir or Madam:

I wish to comment on the record-keeping requirements for 21CFR361.1. As a member of FDA's Radiopharmaceutical Advisory Committee in the early 1970's, I played a major role in conceiving what became 21CFR361.1 in the first place, and have been a member or Chair of a Radioactive Drug Advisory Committee (RDRC) ever since.

FDA took over metabolic and radiopharmacokinetic research using tracers in 1975, when the Atomic Energy Commission (AEC) and later the Nuclear Regulatory Commission (NRC) pressured FDA into doing so in order that the AEC/NRC could stop regulating this research. The plan at the time was to end AEC/NRC's Medical Program, leaving it with State Boards of Medicine and Pharmacy to regulate. *Although FDA has never had any actual statutory authority over such tracer use for basic research—the Food, Drug and Cosmetics Act's definition of a "drug" does not include this use of tracers—the* FDA complied with the request of the AEC and members of the regulated Nuclear Medicine community helped create the regulatory framework with which to accomplish this. Unfortunately, NRC changed its mind, never gave up the regulation of basic research using tracers, and so for 25 1/2 years we have had pointless redundancy of regulation of basic research using tracers. In fact, all such research projects are reviewed by an Institutional Review Board (IRB) which answered to OPRR and now answers to OHRP, a Radiation Safety Committee which answers to the NRC or an Agreement State Radiologic Health entity for byproduct material and a State Radiologic Health entity for accelerator-produced material, *and* a Radioactive Drug Research Committee (RDRC), which answers to the FDA. The redundancy between the Radiation Safety Committee review and the RDRC review is so complete that often the RDRC members are also members of the Radiation Safety Committee and the reviews are done together. Records are kept for the radiologic health entity and other records (containing useless information and outdated concepts) for the FDA. Redundancy in itself serves no purpose, and considering the incredible safety of this type of research, such extreme overregulation is ridiculous. *The extensive paperwork requirements of FDA for 21CFR 361.1 have never been used for a single valuable safety purpose or intellectual purpose in just over a quarter of a century, and should be completely removed. There is no reason why we should not go back to the system we had before the RDRC, which is IRB*

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and Radiation Safety Committee, effectively removing FDA from a loop in which it has never belonged and for which it has never contributed anything to the nation except useless bureaucracy. The use of tracers containing nonradioactive isotopes, such as carbon-13 and deuterium, for metabolic research requires only IRB review, which is appropriate. The addition of a Radiation Safety Committee review if the tracer is radioactive is quite sufficient. The FDA should have no role whatsoever unless a manufacturer wishes to sponsor a clinical trial to determine whether a potential drug is suitable for commercial development.

I therefore recommend that all paperwork requirements of 21CFR361.1 be removed and that the regulation itself be rescinded.

Thank you for your attention and consideration.

Sincerely,



Carol S. Marcus, Ph.D., M.D.
Prof. of Radiological Sciences and of Radiation Oncology, UCLA

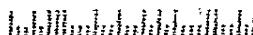
Cc: Interested Parties

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